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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,988	12/09/2003	Suresh K. Arya	4239-67517	9402

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/731,988

**Applicant(s)**

ARYA, SURESH K.

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-17,21 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-15,17,21 and 43-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/9/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1648

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 7-15, 17, 21, and 43-46) in the reply filed on September 2, 2004 is acknowledged. The traversal is on the ground(s) that the inventions are not functionally different. This is found persuasive in part. Claims 17 and 21 are rejoined for examination.

Claims 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. This claim requires the start-stop codon in the gag gene which is not required for the elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-15, 17, 21, and 43-46 are under consideration.

### ***Priority***

The Office acknowledges the preliminary amendment that updates the first line of the specification. It is noted that the parent is now US6790657 and it is requested that the first line be amended to reflect this fact.

### ***Information Disclosure Statement***

Art Unit: 1648

A signed and initialed copy of the IDS filed December 9, 2003 is enclosed.

### ***Claim Objections***

Claim 15 is objected to because of the following informalities: "synctia" appears misspelled. Appropriate correction is required.

Claim 10 appears to fail to further limit claim 9 because more could be deleted.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-15, 17, 21, and 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of derived in claim 7 are not clear because it is not clear when a structure is no longer HIV-2 or when a structure becomes an HIV-2 packaging vector. It is not clear what is meant by functional deletions, it appears that the deletions are all in fact deletions. Packaging functions may be eliminated but deletions are deletions. It is also not clear what is meant by "substantially eliminate" because eliminated is either all or none.

It is not clear in claim 17, last line, what is meant by "HIV-2 virions". The packaging vector of line 1 is not packaged, not a virion. A virion is virus and a virus can have genomic RNA packaged so it is not clear what is meant.

In claim 15, "decreases" relative to what. The function of syncytial formation is dependent on structure, no specific structure is defined or change in structure to decrease syncytia formation.

In claims 21 and 43 it is not clear what is meant by "cell". Is this an isolated cell?

Claims 7, 8, 10, 14, 15, and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genus of double deletions of packaging signals and require elimination of packaging of progeny virus. The specification does not teach what structural elements of the signals are necessary to modify the function as required by the claims. One of skilled in the art cannot predict what modifications will be necessary to obtain the modified function. The specification reduces to practice only one species within the genus, the SD36 (Figure 8). Since the genus embraces a wide variety of deletions, the limited number of species is not seen as representative for the full genus claimed. Claim 8 requires deletion of 1- 164 nucleotides upstream of the SD and 1- 62 downstream. In each set these mutations can occur in singles, pairs, triples, etc. and then for upstream and downstream mutations can occur independently. The skilled artisan cannot envision which single mutations (one nucleotide upstream and one nucleotide downstream) that have the desired function.

Claims 7, 8, 11, 14, 15, 17, 21, and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SD36 (deleted regions as recited in the first specific construct listed in claim 9), does not reasonably provide enablement for all deletions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The invention is drawn to HIV-2 packaging vectors with deletions upstream and downstream of the major splice donor site and the splice donor site is still functional.

As taught by Poeschla *et al.* and MacCann *et al.* (see below) packaging vectors and HIV-2 packaging signals were known in the art. It is clearly shown that packaging signals upstream of the splice donor are more important as shown by MacCann *et al.*

In the instant case, other than SD36, the instant specification is not-enabled for such all deletion mutations as possible by the claims. Claim 8 requires deletion of 1-164 nucleotides upstream of the SD and 1-62 downstream. In each set these mutations

can occur in singles, pairs, triples, etc. and then for upstream and downstream mutations can occur independently.

While deletion of certain regions is known (see MacCann *et al.* below), it would require undue experimentation to determine what the range of mutations are that have the recited function.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-15, 17, 21, and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poeschla *et al.* (from IDS, JV 1998) and MacCann *et al.* (JV 1997, from IDS).

The invention is drawn to HIV-2 packaging vectors with deletions upstream and downstream of the major splice donor site and the splice donor site is still functional.

MacCann *et al.* teach that mutations upstream and downstream of the splice donor site play a role in packaging, not just the sequences downstream of the splice donor as in HIV-1 (Figure 1 and Figure 4C).

Poeschla *et al.* teach that vectors can be made with the 3 prime LTR deleted (pE41, page 6528, column 2, middle), that constructs can have a heterologous

Art Unit: 1648

promoter, including CMV (Figure 1C), and that syncytial formation depends on the packaging signal (Figure 2).

One of ordinary skill in that art at the time of invention would have been motivated to combine the deletions in order to obtain at least an additive effect of reduced packaging. One of ordinary skill in that art at the time of invention would have known about the art of construction of packaging vectors from the HIV 1 and 2 vectors in the art to be able to construct vectors that express proteins needed to package HIV vectors. One of ordinary skill in the art would have known that if the deletions were tolerated and resulted in a change of packaging, then mutating the sequence to non-homologous sequences would work as well. The deletions taught in the prior art overlap the regions claimed and barring unexpected results from specific combinations, the prior art makes obvious modifications that retain the splice donor and gag initiation but change the regions associated with packaging.

Thus, it would have been *prima facie* obvious to make an HIV-2 packaging vector with mutations upstream and downstream of the packaging site.

### ***Conclusion***


No claim is allowed.

Art Unit: 1648

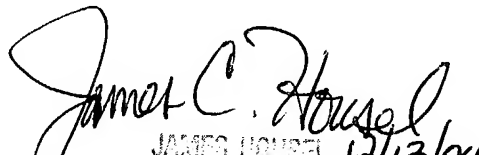
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill  
Patent Examiner  
10 December 2004



JAMES HOUSEL 12/13/04  
SUPERVISORY PATENT EXAMINER  
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